Atrion Medical Products, Inc.
1426 Curt Francis Road
Post Office Box 564
Arab, AL 35016
Tel 205 586 1580
Fax 205 586 8529

K020353

APR 2 5 2002

Atrion Medical

12. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: January 28, 2002

Device Name: Atrion Medical QL™ Fluid Dispensing Syringe

Classification Name: Piston Syringe

Manufacturer: Atrion Medical Products, Inc.
PO Box 564, 1426 Curt Francis Road
Arab, AL 35016

Contact: Mr. Dan Clark, Atrion Medical Products, Inc.
PO Box 564, 1426 Curt Francis Road
Arab, AL 35016
Telephone: (256) 586-1580, ext. 220, Fax: (256) 586-8529
Email: dclark@atrionmedical.com

Predicate:
Atrion Medical Products Balloon Catheter Inflation Device, cleared for market on October 10, 1997 under 510(k) submission K972964. The new device will have the same intended use as the Monarch (IN 2125)/Intellisystem (IN 1125), which was cleared for market on November 25, 1997 under 510(k) submission K973230.

Device Description/Intended Use:
The Atrion Medical QL™ Fluid Dispensing Syringe consists of a plastic syringe with a screw-type plunger and a locking lever and rotating palm grip that control the plunger, a manometer to measure pressure and a connecting tube.

The syringe is intended for single use by healthcare professionals to dispense fluids to the body and monitor the pressure of those fluids.

Technological Characteristics:
The Atrion Medical QL™ Fluid Dispensing Syringe has an operating pressure range of vacuum to gauge capacity, depending on the manometer attached, while the predicate device has a range of vacuum to 10 or 20 atm, depending on the manometer attached. There are no other significant technological characteristics that distinguish the two devices, and no differences that should pose a risk to patient safety.

Summary of Safety Testing:

The materials of the device which contact the solution in use have been tested using USP guidelines and the results of these studies indicate that the product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2002

Mr. Dan Clark
Vice President Regulatory and Quality
Atrion Medical Products, Inc.
P.O. Box 564, 1426 Curt Francis Road
Arab, AL 35016

Re: K020333
Atrion Medical QL™ Fluid Dispensing Syringe
Regulation Number: 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II (two)
Product Code: 74 DXT
Dated: January 28, 2002
Received: January 31, 2002

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

13. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 020333

Device Name: Atrion Medical QL™ Fluid Dispensing Syringe

Indications For Use:

The syringe is intended for single use by healthcare professionals to dispense fluids to the body and monitor the pressure of those fluids.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020333

(Optional Format 1-2-96)